

Washington State Department of Health Guidelines for Investigating Clusters of Chronic Disease and Adverse Birth Outcomes

Revised January 2001

The primary purpose of these guidelines is to assure a coordinated and standardized response from Washington State Department of Health (DOH) employees receiving calls from the public, health professionals, or others about potential clusters of chronic disease and birth outcomes. Coordination within DOH is necessary, since a caller may describe the concern to more than one unit within DOH. The guidelines are also intended to be a reminder to DOH personnel about the importance of communicating and coordinating with the local health agency that has jurisdiction over the geographic area where the potential cluster occurs.

This protocol pertains only to clusters of non-infections diseases, such as cancer and birth defects. It does not apply in emergency situations such as infectious disease outbreaks, bioterrorism events, or radiation accidents.

The process described below for the most part parallels the cluster investigation guidelines published by the Centers for Disease Control and Prevention (CDC) in the July 1990 *Recommendations and Reports* series of Morbidity and Mortality Weekly Report (MMWR). The CDC report contains significantly more detail than the general guidelines presented here.

Although a linear process is outlined below, investigative elements presented under specific stages in this document may in practice occur at other stages. The process is rarely strictly linear.

STAGE 1: COLLECT INITIAL INFORMATION AND PROVIDE EDUCATION AND INFORMATION TO THE INFORMANT.

1. The DOH person taking the initial phone call obtains sufficient information to complete the "New Cluster" page in the cluster database located on the DOH intranet at <http://192.230.1.18/epi/cluster>. In addition to the specified fields identifying the caller, the person taking the phone call should obtain the following information for the "caller's statement" box:
 - type of illness(es)
 - number of people reported with the same illness
 - the ages of the people affected
 - time period during which people became ill
 - where the alleged cluster has occurred
 - whether the caller suspects a specific environmental exposure
 - others the caller contacted about the cluster (include other DOH personnel and other agencies)
 - Organizational affiliation of the caller (e.g., health official, private physician, concerned citizen, employer representative, etc.)

If the concern is outside the area of knowledge of the person taking the initial phone call, the call may be referred to the appropriate person listed in Attachment 1, who

returns the call and completes the “New Cluster” page in the cluster database. It is the responsibility of the person taking the call to obtain information so that DOH can return the call. The caller should not simply be referred to another person in DOH.

In many cases DOH staff may be able to give information which satisfies the informant during this initial call. Often, people just need help understanding and interpreting their observations. Use Attachment 2 (“Talking Points”) for guidance.

2. Decision Point

Following the phone conversation, the person taking (or returning) the call, contacts the local health jurisdiction¹ and others as appropriate (e.g., others in DOH or Labor and Industries) to determine whether to close the case or investigate further. He/she should also check the DOH cluster database (intranet URL above) to see if a similar cluster has been previously reported in the area of concern. If so, the investigator should use professional judgement in determining whether to include previous cases in the current cluster investigation.

a) Criteria for continuing the investigation and moving to Stage 2 include:

- I. There are at least 3 cases of the same or similar conditions, or in the case of birth defects, developmentally similar conditions, OR
- II. A specific exposure of concern, including a potential route of exposure, is alleged as the cause of the cluster.

b) When a decision has been made, the DOH staff member:

- I. Notes in cluster database that case is closed or that further investigation is being considered;
- II. E-mails a short synopsis of the call to
 - the DOH staff listed in Attachment 1,
 - the local health jurisdiction (local health officer, assessment coordinator, or other local health contacts)
 - L&I Safety and Health Assessment and Research for Prevention (SHARP), if the concern occurred in an occupational setting, and
 - DOH or LHJ environmental health officials, Department of Ecology, or other appropriate groups of the concern and the decision made; if the reporting of the cluster was triggered by a specific environmental concern

Personal health information is confidential. To protect patient privacy, all e-mail communications within DOH and between DOH and outside agencies should omit personal identifiers.

- III. Provides feedback to the caller. If the investigation is closed, a written response should be sent. The letter should summarize the concern, the information provided and referrals for environmental assessment, if appropriate. The local health officer or his/her designee and others should review the letter as appropriate before sending. A copy should be sent to

¹ Local health jurisdiction refers to the local health officer and other local health personnel, e.g., administrative director, epidemiologist, assessment coordinator, or environmental health director. DOH will always notify the local health officer at this stage of the investigation. DOH may also notify other local health jurisdiction contacts. If the investigation proceeds to additional stages, the local health jurisdiction will determine who the primary local health jurisdiction contact will be for DOH.

- Non-Infectious Conditions Epidemiology (NICE) to be filed in a central file.
A sample letter and fact sheet for cancer are in Attachment 3.
- IV. Notifies the DOH media office if media involvement is anticipated.

STAGE 2: ASSESS THE MAGNITUDE OF THE REPORTED CLUSTER.

If the investigation is not closed in Stage 1, the person handling the call confirms the need for further action with the Director of NICE. The Director of NICE confers with the people listed in Attachment 1 to determine who within DOH should be involved on the cluster investigation team. This decision is based on skills, availability, and approval by the team members' direct supervisors. The local health jurisdiction (LHJ) is invited to participate on the team and to take the lead. (If the concern were occupational in nature, L&I would be encouraged to participate on the team and take the lead.) If the LHJ does not take the lead, the DOH team designates a lead person who is responsible for coordinating information gathering, keeping a hard copy file of materials, keeping other team members informed and communicating with the caller. However, for continuity, the team leader may designate a contact person other than him/herself for responding to the caller. If the local health jurisdiction or other agency takes the lead, DOH team members decide on a DOH lead who is responsible for communicating with the lead agency, maintaining DOH paper records, and communicating with other DOH team members.

Stage 2A. Preliminary Assessment

Goal: Provide a quick, rough estimate of the likelihood that a statistically significant excess has occurred.

1. The team develops an initial case definition and gathers information on the natural history of the disease, common risk factors, and background rates (if readily available). Also at this time, the team may ask the informant to assist in gathering additional information.² If the diagnosis can be confirmed using readily available data, the team should do so. However, if this is not possible, all reported cases are assumed to be real.
2. If there is a specific exposure of concern, a review of scientific literature and consultation with other investigators or experts may be necessary at this stage. The purpose of the literature review is to assess biologic plausibility, strength, consistency, temporal association and evidence of a dose-response gradient to support an association between the reported exposure and disease.
3. Use standard methods to calculate preliminary observed vs. expected numbers or age-adjusted rates using pre-existing data and/or community reports.
 - a) Define the appropriate geographic area and time period in which to study the cluster.
 - b) Determine the most appropriate reference population available using pre-existing data.
 - c) The geographic area and/or the reference population should be large enough to include all persons at risk of disease. Defining the reference population too narrowly can result in the false identification of a cluster.

² Although the "Initial Inquiry Report Form " (see Attachment 4) was developed for use by communities conducting their own investigations, it may also be useful when asking the informant to gather additional information.

4. **Decision Point**

The cluster investigation team meets to discuss the information gathered and to decide whether to take the investigation to Stage 2b.

- a) **Criteria which serve as guidelines for beginning Stage 2b include the reporting of a least **three** cases of the same condition, a suggested excess of cases, AND one or more of the following:**
 - I. The disease is of known etiology and exposure to the causal agent may exist OR
 - II. The reported exposure has previously been associated with the reported condition OR
 - III. The disease is of unknown etiology and unusual exposures exist in this instance (i.e., these exposures are unique to an area or an occupation and are not commonly found in the US), OR
 - IV. The disease is extremely rare.
- b) When a decision has been made, the following activities occur.
 - I. DOH lead staff member writes a brief note in the cluster database describing investigative activities, and notes that the case is closed or that further investigation is being considered;
 - II. DOH lead staff member e-mails a short synopsis of the decision to the DOH staff listed in Attachment 1. Other team members determine how best to notify other parties who may have been consulted during Stages I and 2a.
 - III. The team lead or other designated team member provides feedback to the caller. If the investigation is closed, a written response should be sent. The letter should summarize the concern, the steps taken during the preliminary assessment, the results of investigative activities, and the rationale for closing the investigation. The local health officer, other team members, and any consultants (e.g., Ecology or SHARP) should review the letter before sending. A copy should be sent to NICE to be filed in a central file.

Stage 2B: Verify initial assessment

Goal: Verify the initial assessment with a more refined analysis of both health and environmental data.

- 1. The team may expand its membership to include DOH and local health jurisdiction personnel who could contribute to the development and implementation of activities at Stage 2b. The team members, in coordination with their supervisors, decide on whether and how the team needs to be expanded, including decisions on public involvement.
- 2. The cluster investigation team develops a plan for verifying the reported illnesses, as well as the exposure of concern (if one has been reported). Typically, the following steps will take place during this stage.
 - a) If indicated, refine the geographic area and time period of interest. The refinements should be based on information gathered during Stage 2a concerning latency periods, available data (both geographically and temporally) and plausibility of exposure to the risk of concern.

- b) Obtain information on all reported cases to verify diagnosis, time of onset and exposure profile. If this step is relatively easy and inexpensive, it may be carried out before step 3 in Stage 2a above.
- c) If necessary, refine the case definition.
- d) Active Case Finding - To ensure that case ascertainment is complete, this step may involve reviewing additional databases or medical records, or obtaining additional information from the community. Generally, obtaining additional information from the community would NOT be a formal survey. Formal surveys generally occur in Stage 4 and investigators need to be careful about not biasing people who may eventually be recruited for Stage 4 activities. For the same reason, investigators need to be cautious in using the media or other public notification procedures to ascertain cases.
- e) Determine whether there is an excess using standard analytic methods such as comparison of rates or the observed and expected number of cases. Additional analytic methods may be useful if denominator data are unavailable, if the area of interest does not correspond to standard geographies, or if more sophisticated analyses involving techniques such as Bayesian smoothing are desired. For consultation on spatial analysis, contact the DOH spatial epidemiologist or NICE. (See Attachment 1.) The statistical tests outlined in the CDC guidelines may also be useful. A description of these tests is available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001798.htm>. The ATSDR Cluster 3.1 software provides additional analytic techniques. Copies of this software are available from NICE.
- f) Assessment of exposure - In cluster reports where a specific potential source of exposure is indicated, a preliminary environmental health assessment should be conducted. This assessment may include a site visit, a review of existing data including engineering and other land-use records, and a review of any existing environmental sampling data. Activities at this stage typically will **not** involve the collection of new data through environmental sampling. If potential exposure sources are verified, exposure pathways and biological plausibility of the suspected contaminants as etiologic factors for the disease need to be delineated.
- g) A review of existing information regarding other risk factors for the condition (e.g., lifestyle or genetic factors) may be completed at this time. As with environmental exposures, activities at this stage typically will **not** involve the collection of new data, such as conducting surveys or collecting biological samples.

3. Decision Point

The cluster investigation team meets to discuss the new information gathered and to decide whether to take the investigation to Stage 3. Since further activities are likely to be resource intensive, a consensus about the decision is important, including support by management within DOH and the local health jurisdiction.

- a) **Criteria which serve as guidelines for moving to Stage 3 include the following (Note: It is recommended that ALL of the following criteria be met):**
 - I. At least 5 cases of the disease.
 - II. An O/E ratio (the ratio of the number of observed cases of the disease to the number of expected cases) that decreases as the number of cases increases,

beginning with an O/E ratio of 20 for 5 cases and ending with an O/E ratio of at least two. To determine the O/E ratio for a specific number of cases, divide 100 by the number of cases. If the result is less than 2, use 2 as the criterion. The following table illustrates results using this method.

Number of cases	Minimum O/E
5	20.0
10	10.0
15	6.7
20	5.0
25	4.0
40	2.5
>50	2.0

- III. The investigation is likely to have a public health impact. For example, a cluster in which data suggest the cause is an environmental contaminant that has already been cleaned up would not require further study³ other than to confirm adequate decontamination. A cluster in which data suggest a stable persistent problem could indicate the need for further study.
- IV. For diseases of **known or suspected etiology**, there must be a plausible exposure and route of exposure, including proper latency between the exposure and the onset of disease.
- V. For diseases of **unknown etiology**:
 - There must be a unique exposure (i.e., an exposure which is not commonly found in the US) and a plausible route of exposure, AND
 - The weight of the evidence from scientific literature should not render an association between the disease and the exposure highly unlikely.

Note: The experience of the California Birth Defects Monitoring Program shows that an investigation is unlikely to uncover a new teratogen unless the following conditions are met:

- There is a large excess of the same defect, with a relative risk 10 or more times the expected rate.
- There is a biologically plausible exposure, including exposure to the teratogen at the critical period of organogenesis. (The critical period varies depending on the organ or organ system involved.)
- There is an unusual pattern of anomalies. Because each teratogen acts on specific tissues and organs, the resulting defects tend to show characteristic patterns. For example, the rubella virus causes heart defects, cataracts, chorioretinitis, deafness and developmental disabilities, while thalidomide causes limb defects.

- b) When a decision has been made the following activities occur.
 - I. The DOH lead staff member writes a brief note in the cluster database, noting that the case is closed or that further investigation is being considered.
 - II. DOH lead staff member e-mails a short synopsis of the decision to the DOH staff listed in Attachment 1. Other team members determine how best to notify other parties who may have been consulted.

³ However, if the effects of a historical exposure could be mitigated by a specific action, investigators should notify those who had been at risk of exposure.

- III. The team lead or other designated team member provides feedback to the caller. If the investigation is closed, a written response should be sent. The letter should summarize the concern, the steps taken during stage 2, the results of investigative activities, and the rationale for closing the investigation. The local health officer, other team members, and any consultants (e.g., Ecology or SHARP) should review the letter before sending. A copy should be sent to NICE to be filed in a central file. Copies of the letter may also be forwarded to other agencies, such as Department of Ecology, which have become involved through the review of existing data.

STAGE 3: DETERMINE UTILITY AND FEASIBILITY OF FURTHER EPIDEMIOLOGIC STUDY

Goal: Determine the feasibility of performing an epidemiologic study linking the health event and a putative exposure.

1. Having verified through Stage 2 activities that there is an excess number of cases of a specific illness (or illnesses) in the defined community/population and that further investigation may be warranted, the first step in Stage 3 is to determine whether the team needs to be expanded to include others within DOH; the local health jurisdiction; other state agencies which may be involved in environmental sampling, such as the Department of Ecology or the Department of Agriculture; the members of the community and/or persons with specific areas of expertise, such as CDC, university personnel and other state health departments. The team members, in coordination with their supervisors and the Director of NICE, decide on whether and how the team needs to be expanded.
2. The team's main objective is to review the information obtained in the investigation up to this point and examine the potential for relating the observed cluster to a specific exposure.

As outlined in the CDC guidelines, the following steps may be undertaken in this process:

- Consider appropriate study designs, with attendant costs and expected outcomes.
- Determine what data should be collected, including environmental samples and physical and laboratory measurements. Consider the logistics of data collection.
- Consider the potential social, financial and environmental implications of different decisions and study outcomes.
- Estimate total resources required by the study itself and by alternative study findings.

NOTE: According to Rothman (AJE, 1990) systematic studies of clusters of diseases are not likely to be feasible unless

- The disease is **extremely** rare, AND
- The frequency of the disease has **suddenly** increased

NOTE: Other characteristics which indicate that an investigation might be fruitful include:

- The etiologic agent is easy to measure:
 - ✓ It persists in the environment
 - ✓ It is detectable and measurable

- ✓ It is rare in the general population and leaves a physiological response in the bodies of those exposed
 - There is an ability to select an appropriate control group, i.e., the exposure is heterogeneous.
3. If the team decides an etiologic investigation is warranted and feasible, the investigation proceeds to the next stage. Otherwise the team's findings are summarized, written reports are sent to the initial informant and other concerned parties; detailed case-closure reports are filed in the lead's file, with NICE, the local health jurisdiction, and other involved parties and a brief note is made in the database.

STAGE 4. CONDUCT DETAILED ETIOLOGIC INVESTIGATION

Goal: To perform an etiologic investigation of a potential disease-exposure relationship.

1. The primary purpose of this stage of the investigation is to pursue the epidemiologic or public health issues that the cluster generated. In this context, this stage represents a standard epidemiologic study, for which all the preceding work has been preparatory.
2. Based on the information collected and decisions made in Stage 3, develop a protocol and implement the study. At this point the remaining investigative steps will be unique to each study and further guidelines are outside the scope of this document.
3. Share the results of the investigation with the community and other appropriate groups. When appropriate, recommend interventions to address the issue.

HELPFUL REFERENCES

1. Guidelines for investigating clusters of health events. MMWR, July 27, 1990/39(RR-11);1-16.
2. Cancer Epidemiology and Prevention, Second Edition, Schottenfeld, D and Fraumeni, JF, eds. 1996, Oxford University Press, New York, NY.
3. Dwyer DM, Strickler H, et al. Use of case-control studies in outbreak investigations. Epi Rev 1994;16(1):109-123.
4. Caldwell GG. Twenty-two years of cancer cluster investigations at the Centers for Disease Control. AJE 1990 July;132(S1): S43-47.
5. National Conference on Clustering of Health Events. AJE 1990 July;132(S1).

ATTACHMENT 1: DOH Contacts for Cluster Calls**Cluster types**

Birth defects, reproductive problems, other maternal and childhood conditions

Cathy Wasserman	(360) 236-3542	cathy.wasserman@doh.wa.gov
Riley Peters	(360) 236-3495	riley.peters@doh.wa.gov

Cancer

Juliet VanEenwyk	(360) 236-4250	juliet.vaneenwyk@doh.wa.gov
Mahesh Keitheri Cheteri	(360) 236-3669	mahesh.keithericheteri@doh.wa.gov
Katie Golub	(360) 236-3624	kathryn.golub@doh.wa.gov

Environmental concerns (with or without specific identified health concerns)

Jim VanDerslice	(360) 236-3183	jim.vanderslice@doh.wa.gov
Judy Bardin	(360) 236-3193	judy.bardin@doh.wa.gov
Glen Patrick	(360) 236-3177	glen.patrick@doh.wa.gov

L&I contact for occupational concerns

Barbara Silverstein	(360) 902-5668	silb235@lni.wa.gov
Dave Bonauto	(360) 920-5664	bone235@lni.wa.gov

Other

Juliet VanEenwyk	(360) 236-4250	juliet.vaneenwyk@doh.wa.gov
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Commonly used datasets

Birth Certificates

Pat Starzyk	(360) 236-4323	pat.starzyk@doh.wa.gov
Joe Campo	(360) 236-4321	joe.campo@doh.wa.gov

Comprehensive Hospital Abstract Reporting System (CHARS)

Gary Blair	(360) 236-4212	gary.blair@doh.wa.gov
Ann Lima	(360) 236-4351	ann.lima@doh.wa.gov
Joe Campo	(360) 236-4321	joe.campo@doh.wa.gov

Death Certificates

Phyllis Reed	(360) 236-4324	phyllis.reed@doh.wa.gov
Joe Campo	(360) 236-4321	joe.campo@doh.wa.gov

Washington State Cancer Registry

See "Cancer" above.

NICE contact for general questions

Juliet VanEenwyk	(360) 236-4250	juliet.vaneenwyk@doh.wa.gov
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Spatial Epidemiology

Dick Hoskins	(360) 236-4270	richard.hoskins@doh.wa.gov
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Attachment 2: Talking Points

The initial contact is often DOH's best opportunity for informing the caller about the problems inherent in investigating clusters. Here are some points to keep in mind during this first encounter (based on the CDC guidelines):

General

- Except for **very** rare diseases, statistically significant disease "clusters" usually occur by chance alone and are not related to a specific exposure. That is to say, each case in the cluster probably has a different cause, even though the cases have clustered together in time and/or space.
- There are usually many other communities with similar exposures who are not reporting a cluster.
- Cases among persons now deceased may not be helpful in linking exposure to disease because of the lack of information on exposure and other important factors.

"Nature of Studies" Information

- It's difficult, if not impossible, to reconstruct exposure histories. This is especially true for diseases with long latency periods between exposure to a disease-causing agent and the onset of disease symptoms. What's in the air or water today may not be what was in the air or water several years or decades ago.
- It's difficult to detect subtle effects, especially when the number of cases is small. If the relationship were strong, we would expect to have seen an association in other places, such as workers, where exposures are higher.
- For diseases of unknown etiology, we don't know what to look for, unless there is a **unique** exposure of concern.

To prove a causal relationship between an exposure and a disease, there must be a body of evidence gathered over many years. One study documenting a cause-effect relationship is only suggestive.

Regarding cancer:

- Cancer is a common illness that increases with age and so cases among older persons are less likely to be true clusters.
- There are many different types of cancer, which are the result of a wide variety of causal mechanisms. A variety of diagnoses speaks against a common origin.
- Both nationally and in Washington, 25% of people die of cancer and between 25 and 33% of people develop cancer at some point in their lives.
- A cancer that spreads to another part of the body should not be considered a new case of cancer. For example, if a breast cancer that has been in remission recurs in the lung, this is not considered to be a new lung cancer, but a primary breast cancer that has metastasized to the lung. Cancer from other sites often spreads to the brain, liver or lung.
- Some types of cancers (such as lymphomas and bone cancer) may occur anywhere in the body. They should not be classified according to where they appear in the body.

For example, a non-Hodgkin's lymphoma may manifest itself in the brain, but it is not a brain cancer. A cancer in the skull is not a brain cancer.

- Length of time in residence must be substantial to implicate an environmental carcinogen because of the long latency period (i.e., the time between exposure and development of the cancer) required for most known carcinogens. Latency periods may be as short as 6 months to 5 year for some exposures, such as leukemia from exposure to radiation from a nuclear bomb, but generally, latency periods are much longer. For example, lung cancer generally develops 20-40 years after the initiation on smoking.
- The causes of many types of cancer are unknown.

Regarding Birth Defects:

- Major birth defects are less common than cancer but still occur in 1-2% of live births.
- There are roughly 80,000 births in Washington per year, so we could expect to see 800 to 1600 infants born with major birth defects per year in our state.
- The causes of most birth defects are unknown.

Provide Useful Information for Reducing the Risk of Chronic Disease

- Don't smoke or chew tobacco
- Eat at least 5 servings per day of fruits and vegetables
- Limit the amount of fat – especially saturated fat – in your diet
- Regular exercise is important – at least 30 minutes of moderate exercise 5 times a week
- Limit alcohol intake
- Protect yourself from sunburn
- Follow recommended guidelines for preventive services and screening for early detection and treatment, such as screening for colorectal, cervical and breast cancer, high blood pressure and high cholesterol.

Attachment 3: Sample letter and fact sheet

DOH Letterhead

[Date]

[Address]

Dear [Caller],

Thank you for your recent report about cancer in your [neighborhood/workplace/school]. You are not alone in having questions and concerns about cancer in Washington State. We receive many inquiries from people who believe they are seeing a high rate of cancer in their community, workplace, or school.

The Washington State Department of Health has a Cluster Investigation Work Group that reviews reports like yours to determine whether investigation would be likely to identify a cause for the cancer cluster. Several members of this group reviewed your report. We believe the information you provided does not suggest a common cause for the cancers and that further investigation is not likely to give us new clues about the cause of these cancers.

Unfortunately, no one can say with certainty what caused any one person's cancer. We can only talk in general terms about the known and suspected factors that increase a person's risk of developing a specific cancer type. Most of our knowledge about cancer causes comes from studies comparing many people with the same cancer to people who do not have cancer. Investigations in relatively small communities shed light on the cause of cancer only under very rare conditions.

After years of responding to citizen cancer reports, the Department of Health has learned that many concerns come from common misunderstandings about cancer. Specifically, many people are unaware of how frequently cancer occurs and what increases the risk of developing cancer. A fact sheet on cancer and cancer clusters is attached to this letter.

I hope this letter and the enclosed fact sheet are helpful. Again, thank you for contacting the Department of Health.

Sincerely,

[Lead Investigator]

[Title]

[Office or Department]

[Address]

[Phone number]

Enclosure

cc Maxine Hayes, MD, Washington State Health Officer

Cancer Facts and Cancer Clusters

What is a cancer cluster?

A cancer cluster is an unusual number of cancers occurring during a specific time period among people who live or work together. The impression that a cancer cluster exists usually begins when someone's spouse, neighbor, or friend is diagnosed with cancer. This close contact with cancer often brings an awareness of others who have cancer and a desire to answer the question, "Why?" It is not uncommon for people to suspect the cancer cause is a chemical in the environment. Increased awareness about cancer and the search for a cancer cause may lead someone to contact the Department of Health. The following cancer facts might help answer some of your questions about cancer.

Cancer Facts

Cancer is more common than most people realize.

Cancer is the second leading cause of death in Washington and in the United States, following heart disease. According to the American Cancer Society, about 30% of Americans now living will eventually have cancer. Over the years, cancer will strike about three out of four families. Given these statistics, it is not surprising to know several people in a neighborhood or workplace who have cancer.

Cancer is not one disease.

Cancer is a group of more than 100 diseases characterized by uncontrolled growth and spread of abnormal cells. Different types of cancer have different causes, different rates of occurrence, and different chances for survival. What turns a breast cell into breast cancer isn't what turns a white blood cell into leukemia. Therefore, we cannot assume all the different types of cancer in a neighborhood or community share a common cause.

In addition, even if the cancers seem to be similar, they may not have a similar cause. Cells have a variety of genes that keep them functioning normally and it takes a combination of factors – what cancer biologists call multiple "hits"- to make a cell cancerous. One combination may be a genetic defect combined with an exposure to a cancer-causing agent (also called a "carcinogen"). Another combination may be a lifestyle factor such as smoking combined with a specific viral infection. To further complicate matters, each of these factors can be modified by individual characteristics that are poorly understood. Thus, it is possible that the cases of a certain cancer in a cancer cluster may have causes that are unrelated to each other.

The risk of having cancer increases with age.

While cancer occurs in people of all ages, cancer rates rise sharply among people over 45 years of age. When a community or neighborhood consists primarily of people over the age of 45, we would expect more cancer than in a neighborhood of diverse ages. We would expect even more cancer if most people were over the age of 60.

While the exact cause of most cancers is unknown, the most common types of cancer are associated with lifestyle factors.

Cancer may be caused by a variety of factors acting alone or together over many years. Scientists estimate that most cancers are associated with factors related to how we live, called lifestyle factors. Evidence reviewed by the American Cancer Society suggests that about one-third of the 550,000 cancer deaths that

occur in the United States each year is due to dietary factors (for example, excess calories, high fat, and low fiber). Another third is due to cigarette smoking. Other lifestyle factors which increase the risk for cancer include drinking heavily, lack of regular physical exercise, promiscuous sexual behavior, and sunlight exposure. Some cancers have been associated with certain viral infections. A family history of cancer increases a person's chances of developing some cancers. Finally, occupational exposure to some chemicals increases the risk for a few cancers.

Environmental factors account for a small percentage of all cancer deaths.

Many people believe that cancer is usually caused by exposure to toxic substances in the environment. Contrary to this belief, however, the cancers that occur most frequently are caused by lifestyle factors. We do not know the exact impact of environmental pollutants on cancer development, but scientists at the Harvard School of Public Health estimate that only about 10% of cancer deaths are related to environmental factors such as radiation and toxic chemicals.

Cancers today are usually related to events that happened many years ago.

Cancer does not develop immediately after contact with a carcinogen. Instead, there is often a long period, 15 to 30 years, between the exposure to a carcinogen and medical diagnosis of cancer. This makes it very difficult to track what caused the cancer. The cancers we see now are usually related to a lifetime of certain habits or exposure to a carcinogen many years ago. And, in a mobile society like ours, cancer victims who seem to be clustered may not all have lived in a neighborhood long enough for their cancers to be caused by exposure to a carcinogen in the community environment.

Cluster Facts

Cancer clusters may occur by chance.

Even if there are more people with one type of cancer in a community than might be expected, we cannot assume it was caused by exposure to a cancer-causing agent in the environment. The cluster may have occurred simply by chance. There are several principles to keep in mind when investigating a cluster of cancer:

- **People have a tendency to see patterns in random events.** For example, in a coin toss, people assume that a sequence of 6 "heads" in a row is somehow less random than "head-tail-head-head-tail-tail." But in reality, both sequences are equally likely.
- **People tend to isolate a cluster from its context.** This is known as the "Texas Sharpshooter Fallacy." The Texas sharpshooter shoots at the side of a barn and then draws a bull's-eye around the bullet holes. In the same way, we might notice a number of cancer cases, then draw our population base around the smallest area possible, neglecting to remember that the cancer cases actually came from a much larger population.

To decide whether the number of people with cancer in a reported cluster may be more than expected, epidemiologists use data from state or national cancer registries to calculate an "expected" number of cases. They then compare the "expected" number of cases with the "observed" number of cases by performing one or more statistical tests. In making statistical comparisons – usually at a "95% confidence level" – five of 100 comparisons may be significantly different by chance alone. A typical cancer registry tracks 80 different kinds of cancer. Using these facts, statisticians at the California Department of Health Services have calculated that there is a 98% chance that a given community will show a statistically

significant but totally random elevation in the rate of at least one type of cancer. Thus, even when a statistical test shows there is a “statistically significant” difference between the observed and the expected number of cases, in many instances the significant difference is due to chance and not to a real hazard in the community.

Because it is so difficult to tell a true cancer cluster from a cluster imposter, the Department of Health has developed a “Cluster Investigation Protocol” to determine which cancer clusters might be worth investigating more fully. Oftentimes, studying much larger groups of people will shed more light on the causes of cancer than studying isolated neighborhood or workplace clusters.

The following references are recommended for further information on the causes of cancer and cancer clusters:

1. Trichopoulos, D. et al “What Causes Cancer?” Scientific American, September, 1996. Available online at <http://www.sciam.com/0996issue/0996trichopoulos.html>
2. Gawande, A. “The Cancer Cluster Myth.” The New Yorker, February 8, 1999.
3. The National Cancer Institute’s website, located at <http://www.nci.nih.gov>.
4. The American Cancer Society’s website, located at <http://www.cancer.org>.

Attachment 4
Illness Cluster Investigation
Initial Inquiry Report Form

Cluster ID (400): _____

Date (401): _____

Interviewer

First Name (402)

Last Name (403)

Phone (404)

Office (405) *[e.g. OTS, EPI, MCH, etc]*

Patient Information

First Name (501)
(504)

Last Name (502)

Day Phone (503)

Evening Phone

Sex (505): ☐ Male ☐ Female

Date of Birth (506): _____

Residence Address:

Dates of Residence at this Address:

Street (507)

From (MM/DD/YY) (511)

To (MM/DD/YY) (512)

City (508)

State (509)

Zip (510)

Illness or Disease Information

(601) Disease or Condition

☐ Miscarriage

☐ Still Birth

☐ Birth Defect (specify) _____

☐ Leukemia

☐ Other Cancer (specify) _____

☐ Other Illness (specify) _____

☐ Other non-specific health symptoms _____

(602) Date of Diagnosis: _____/_____/_____
 Month Day Year

Address at Diagnosis:

Street (603)

City (604) State (605) Zip (606)

(607) Usual Job:

(608) Years Worked: _____ Number of Years

(609) Smoking Status

- ☐ Smoker
 - ☐ Past smoker
 - ☐ Never smoked
-

(610) Deceased? ☐ Yes ☐ No

(611) If Yes, Year of Death _____

Place of death:

City (612)

State (613)

NOTE: This form has been supplied by the Washington State Department of Health (DOH) for use by citizens. While information on this form may be reviewed by DOH, the use of the form does NOT constitute an official DOH inquiry. Completion of this form is optional
